

City and County of San Francisco

Department of Public Health



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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane,
Rm. 1061
Rockville, MD 20852

October 22, 2002

RE: FDA's Request for Comment on First Amendment
Issues published in the Federal Register of May 16, 2002 (67 FR 34942)

To whom it may concern,

Please find a copy of a research study to be published in a forthcoming issue of AIDS describing the potential adverse impact of direct-to-consumer medication advertising.

Persons who had the greatest exposure to these direct-to-consumer advertisements were most likely to falsely believe that HIV was a less serious disease and believed that these medications influenced a persons decision to engage in riskier sexual behavior. Finally, those HIV-infected men who had the greatest exposure were most likely to engage in unprotected intercourse, a risk behavior known to transmit HIV.

This is one of the few research studies to document the direct negative effects of direct-to-consumer advertising.

We fully support the restriction of direct-to-consumer advertising and find no evidence of any educational benefits to the consumer. It is incumbent upon the FDA to protect the public's health and limit misleading and wasteful direct-to-consumer advertising. In addition, we call for changes in regulation that would require an equal share of medication advertising to be used to support local prevention efforts.

Sincerely,

A handwritten signature in black ink, appearing to read "John P. Korman".

Deputy Health Officer

and

Assistant Professor of Medicine, University of California, San Francisco

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found that homosexual men frequently saw HIV medication advertisements. HIV-positive homosexual men with greater advertisement exposure believed HIV was a less serious disease. All men believed these advertisements influenced an individual's decision to have unprotected sex. HIV-positive homosexual men with greater advertisement exposure may be more likely to have unprotected anal intercourse.

Several studies have suggested that HIV treatment optimism may play a role in increasing the rates of unsafe sex among gay men and men who have sex with men [1-4]. Whereas direct-to-consumer (DTC) advertising campaigns for antiretroviral HIV drugs strive to increase the awareness of the potential benefits of HIV therapy, there may be untoward effects of this DTC advertising. A recent publication described 'what Americans are being sold in direct-to-consumer (DTC) advertisements for prescription drugs', but failed to quantify the effects that DTC advertisements may have in specific populations [5]. We sought to quantify these effects in a population with potential high exposure to certain DTC advertising, and measured the relationship between exposure and reported attitudes and behaviors.

From February to July 2001, we surveyed men attending the San Francisco municipal sexually transmitted disease (STD) clinic regarding sexual practices, HIV status, exposure to HIV pharmaceutical advertisements and attitudes towards the seriousness of HIV and a decision to have unprotected sex. The survey was an anonymous, self-administered convenience sample of 997 men, 53% of whom were heterosexual. We compared results between heterosexual ($n = 527$) and homosexual men ($n = 466$) and between homosexual men by HIV status (HIV negative 300; HIV positive 75) by frequency of exposure to HIV pharmaceutical advertisements. We defined seeing advertisements at least weekly as frequent exposure versus monthly, rarely or never seeing advertisements as infrequent exposure. The mean age of respondents was 32 years, 49% were white and 84% had completed at least some college education.

Among homosexual men, 76% reported seeing HIV drug advertisements that portrayed men who are healthy, handsome and strong either daily or weekly versus only 38% in heterosexual men ($P < 0.05$). Whereas the frequency of exposure did not appear to affect men's belief in the seriousness of HIV by sexual orientation, HIV-positive homosexual men who saw advertisements at least weekly were six times more likely to believe that HIV was less serious compared with HIV-positive homosexual men who saw advertisements less frequently (36 versus 6%, $P < 0.03$).

Regardless of sexual orientation, those with more

1287 Are HIV drug advertisements contributing to increases in risk behavior among men in San Francisco, 2001?

Jeffrey D. Klausner^a, Andrea Kim^b and Charlotte Kent^a

In winter 2001, we quantified exposure to HIV medication direct-to-consumer advertising and its relationship to attitudes and behaviors among sexually transmitted disease clinic attendees. We

frequent exposure to the advertisements were more likely to agree that the advertisements affected an individual's decision to have unprotected sex compared with men with less exposure (63 versus 42% in homosexual and 69 versus 56% in heterosexual men, $P < 0.01$, respectively). In addition, among HIV-positive homosexual men with frequent advertisement exposure, 58% reported that these advertisements affected an individual's decision to have unprotected sex versus only 13% in those less frequently exposed ($P < 0.01$).

Finally, we found no difference between homosexual and heterosexual men in reported unprotected vaginal or anal sex by advertisement exposure. Within homosexual men, however, HIV-positive respondents with frequent advertisement exposure more often reported unprotected anal sex compared with HIV-positive respondents with infrequent exposure (27 versus 17%, $P < 0.4$).

We concluded that during the survey period homosexual men in San Francisco seen at the municipal STD clinic were frequently exposed to HIV pharmaceutical advertisements. HIV-positive homosexual men with greater exposure to the advertisements believed that HIV is a less serious disease, and both heterosexual and homosexual men believed that these advertisements influence an individual's decision to have unprotected sex. Finally, HIV-positive homosexual men with greater exposure to these advertisements may be more likely to engage in unprotected anal intercourse.

This study demonstrated that DTC HIV pharmaceutical advertising affects health beliefs at the population level and may influence individual behaviors. Subsequent to the preliminary report of these data, the Food and Drug Administration issued an advisory letter to HIV pharmaceutical manufacturers instructing them to change DTC materials to convey that HIV medications neither cure HIV infection nor reduce its transmission, and that individual medications must be taken only in combination with other drugs for HIV infection. Furthermore, the Food and Drug Administration letter stated that the images used in DTC promotional activities must be generally representative of patients with HIV infection and must not minimize significant side-effects.

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